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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,296	10/10/2000	Douglas D. Randall	UMO-1482.1	4557

321 7590 05/20/2003

SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/20/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/685,296

Applicant(s)

RANDALL ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,8,12,16,20-24,28 and 31-68 is/are pending in the application.
- 4a) Of the above claim(s) 4,8,12,16,20-24,28 and 31-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 29 and 30 have been cancelled. Claims 45-68 have been added.

Applicant's arguments will be addressed to the extent that they read upon newly added Claims 45-68.

The rejections of the Claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of Applicant's amendments and arguments.

#### *Claim Rejections - 35 USC § 112*

Claims 45-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as stated in the last Office action for Claims 29-30.

Applicant asserts that written description objections raised by the Examiner are rendered moot in light of the newly added claims broadly drawn to nucleic acid polymers encoding an enzyme that enhances the biosynthesis of 2-oxobutyrate, or nucleic acid polymers encoding the E1 $\alpha$ , E1 $\beta$ , and the E2 complex of the branched chain oxoacid dehydrogenase, or polynucleotide sequences defined structurally and functionally in that they hybridize to said sequences under moderate hybridization conditions of 55° C and have activity differing by 30% or less when compared to the activity of the *Arabidopsis* sequence (response page 8 line 10 to page 10 line 7). The moderately stringent hybridization conditions of 55° C would recover a multitude of

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structurally and functionally divergent sequences other than those that have a difference of more than 30% activity of the *Arabidopsis* sequence, and thus the written description does not show a correlation between the claimed structure and the claimed function.

Applicant asserts that the citation of Gruys *et al.* WO 98/00557 teaches various enzymes on pages 21 and 42 as well in Figure 3 as an example of the knowledge of one of skill in the art with respect to written description (response page 10 line 1). The Gruys reference teaches SEQ ID NO:s 1 (page 145 lines 17-18), 5, 7 and 8 (page 157 line 18) encoding threonine deaminases modified from the *E. coli* wild type sequence of SEQ ID NO: 1, and SEQ ID NO: 9 (page 193 lines 18-24) encoding a beta keto thiolase polynucleotide isolated from *A. eutrophus*,<sup>but</sup> does not teach polynucleotide sequences encoding the E1 $\alpha$ , E1 $\beta$ , and the E2 complex of any branched chain oxoacid dehydrogenase complex.

Claims 45-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as stated in the last office action for Claims 29-30.

Applicant asserts that Example 7 teaches the combination of the E1 $\alpha$ , E1 $\beta$ , and the E2 complex with the endogenous E3 complex in the plastid of a plant and that the references cited by the Examiner in support of unpredictability in the art with respect to mixing subunits and reconstituting activity are not applicable to the presently claimed invention (response page 10 line 17 to page 12 line 5). The claims read upon a combination of the E1 $\alpha$ , E1 $\beta$ , and the E2 subunits from different species together having a prerequisite activity. Applicant has not

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demonstrated activity of a reconstituted multi-meric complex no less different than 30% of the *Arabidopsis* E1 $\alpha$ , E1 $\beta$ , and E2 activity.

Applicant asserts that the office action cited Osterman et al. for the proposition that the formation of heterodimers is unpredictable, that the reference disclosed that *T. brucei* and mouse ornithine decarboxylase formed heterodimers without sharing exact sequence identity, and that the reference does not properly address the manner in which the subject matter is claimed (response page 12 lines 6-26). The reference disclosed that the formation of heterodimers is unpredictable when mixing subunits from different species. This complexity and unpredictability can only be expected to increase given that the claimed invention is drawn to a triple subunit complex. Furthermore, the maintenance of requisite activity among non-exemplified combinations of subunits from a multitude of non-exemplified species is an invitation to experimentation.

Applicant asserts that the Larson reference teaches that Larson et al. were looking for specific substitutions that could completely alter activity (response pages 13-14). The reference teaches that there are interactions between enzymes that are conserved across a family or species that have co-evolved (i.e. species specific) and hence are required for a productive interaction. In the Larson reference, a P89R substitution in the *Chlamydomonas* Rubisco made the *Chlamydomonas* enzyme look like a tobacco Rubisco, as made evident by the increase in carbamylation when incubated with the tobacco Rubisco activase and the decrease in carbamylation when mixed with the spinach Rubisco activase, when compared to the wild type *Chlamydomonas* Rubisco.

Applicant asserts that the citation of Gruys *et al.* WO 98/00557 teaches various enzymes on pages 21 and 42 as well in Figure 3 as an example of the knowledge of one of skill in the art with respect to teaching one how to make and/or use the invention (response page 14 lines 11-16). The Gruys reference teaches SEQ ID NO:s 1 (page 145 lines 17-18), 5, 7 and 8 (page 157 line 18) encoding threonine deaminases modified from the *E. coli* wild type sequence of SEQ ID NO: 1, and SEQ ID NO: 9 (page 193 lines 18-24) encoding a beta keto thiolase polynucleotide isolated from *A. eutrophus*, <sup>but</sup> does not teach polynucleotide sequences encoding the E1 $\alpha$ , E1 $\beta$ , and the E2 complex of any branched chain oxoacid dehydrogenase complex. Since Applicant has not described the sequences of the instant claims <sup>d</sup> since Applicant's citation of Gruys does not describe the sequences of the instant claims, methods of using those sequences are not taught as well, and thus the claims are not enabled.

Claims 45-68 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest plants containing all of the recited enzymes, either naturally or by transformation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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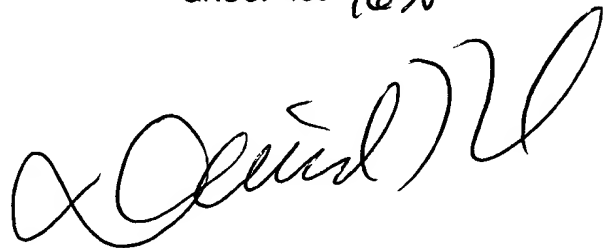
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.  
May 9, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~480~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the typed name and title.